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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,355	10/14/2003	Hanswalter Zentgraf	31304-760.831	6701

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WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER

CROWDER, CHUN

ART UNIT	PAPER NUMBER
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1644

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/686,355

Applicant(s)

ZENTGRAF ET AL.

Examiner

Chun Crowder

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) 5-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendments, filed 11/06/2006, are acknowledged.

Claims 3 and 4 have been canceled.

Claims 1 and 2 have been amended.

Claims 1, 2, and 5-10 are pending.

Claims 5-10 have been withdrawn from further consideration, under 37 C.F.R. 1.142(b), as being drawn to nonelected inventions.

Claims 1 and 2 are pending.

2. This Office Action will be in response to applicant's arguments, filed 11/06/2006.

The rejections of record can be found in the previous Office Action, mailed 07/07/2006.

The text of those Sections of Title 35 U.S.C. not included in this Action can be found in a prior Action.

3. Claims 1 and 2 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Randall et al. (Vaccine. 1993. 12:1247-1252. Reference AM on IDS) in view of Harlow et al. (Antibodies. A Laboratory Manual. 1988. pages 139-147) for reasons of record.

Applicant's arguments have been fully considered but have not been found persuasive.

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Applicant argues that the instant claims have been amended to recited a monoclonal antibody that specifically binds to a histidine portion of a fusion polypeptide, but not to the non-histidine portion of the fusion polypeptide. Randall et al. fails to disclose such a claimed monoclonal antibody. In contrast, Randall focuses on developing vaccines against various recombinant antigens. The tag sequences, a 12-amino-acid-N-terminal His tag (His) and a C-terminal tag (Pk), were merely used as tags for purification of the recombinant proteins for immunization purposes. See Abstract. Nowhere could be found a teaching that a monoclonal antibody was developed against the His tag. Instead, Randall et al. discloses mouse sera which cross-reacted with not only the antigen, but also with both the N and C-terminal tags. Randall et al. fails to teach or suggest the claimed monoclonal antibody that specifically binds to a histidine portion of a fusion polypeptide, but not to the non-histidine portion of the fusion polypeptide. On the other hand, Harlow et al. is a general laboratory manual for generation of monoclonal antibodies. Nowhere do Harlow et al. teach or suggest the claimed antibody specifically against the histidine portion of a fusion polypeptide.

This is not persuasive for following reasons:

It is noted that in considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom In re Preda, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968). See MPEP 2144.01.

Contrary to applicant's assertion that Randell et al. focuse on developing vaccines against various recombinant antigens and the tag sequences, a 12-amino-acid-N-terminal His tag (His) and a C-terminal tag (Pk), were merely used as tags for purification of the recombinant proteins for immunization purposes, Randell et al. clearly teach anti-sera, made by immunizing mice using histidine tagged antigen, contains antibody against N-terminal histidine tag (see entire document, particularly Results on pages 1249-1251).

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Further, in response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combination of references. See MPEP 2145.

Furthermore, specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America 202 USPQ 22 (DC SNY); and In re Burckel 201 USPQ 67 (CCPA). In re Burckel is cited in MPEP 716.02.

Here, given the teachings of Randall et al. regarding the anti-sera contains antibody against N-terminal histidine tag for purification of protein comprising histidine tag, and the teachings of Harlow et al. regarding methods of making and using monoclonal antibodies, the ordinary would have had a reasonable expectation of success of producing monoclonal antibodies against histidine fusion proteins.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The rejections of record are maintained for the reasons of record, as they apply to the amended claims. The rejections of record are incorporated by reference herein as if reiterated in full.

4. Upon further consideration as well as applicant's amendments to the claims and the filing of a terminal disclaimer signed by the assignee and fully complied with 37 CFR 3.73(b), the previous objection and rejections under **35 U.S.C. 102(b), the nonstatutory obviousness-type double patenting, and statutory type double patenting** have been withdrawn.

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5. Conclusion: no claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.

Patent Examiner

January 5, 2007

Phillip Gambel
PHILLIP GAMBEL, PH.D. JD
PRIMARY EXAMINER
TZ 600
1/10/07